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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,241	10/19/2001	Darrell C. Conklin	00-94	7880

7590 02/18/2004

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EXAMINER

RAWLINGS, STEPHEN L

ART UNIT PAPER NUMBER

1642

DATE MAILED: 02/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/038,241

Applicant(s)

CONKLIN ET AL.

Examiner

Rawlings L. Stephen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. The amendment filed February 26, 2002 is acknowledged and has been entered.
2. Claims 1-25 are pending in the application and are currently subject to the following restriction.

#### ***Election/Restrictions***

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-11 and 14, insofar as the claims are drawn to an isolated polynucleotide encoding the amino acid sequence of SEQ ID NO: 2 or a portion thereof, an expression vector comprising said polynucleotide, a cultured cell comprising said expression vector, and a method for producing a protein comprising said amino acid sequence or portion thereof, classified in class 536, subclass 23.4 or 23.5, class 435, subclass 320.1, class 435, subclass 325+, and class 435, subclass 69.1, respectively.

Note: Although claim 8 (b) presently recites, "the amino acid sequence as shown in SEQ ID NO:4" (emphasis added); it is believed claim 8 (b) should read, "the amino acid sequence as shown in SEQ ID NO:2". If Applicant elects the invention of group I, claims 1-11 and 14 will only be examined to the extent set forth above; and accordingly claim 8 will not be examined to any extent claim 8 is drawn a DNA construct encoding a fusion protein comprising a portion of SEQ ID NO: 4.

Group II. Claims 12 and 13, drawn to an isolated polypeptide, classified in class 530, subclass 350.

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Group III. Claim 15-18, drawn to an antibody and a method for producing said antibody, classified in class 530, subclass 387.9, for example, and class 424, subclass 185.1, respectively.

Group IV. Claims 19 and 20, drawn to a method for detecting the presence of an antagonist or agonist of zlmada24 protein activity, which cannot be classified because the zlmada24 protein activity has not been specified or disclosed.

Group V. Claim 21, drawn to a method for detecting a genetic abnormality in a patient, classified in class 435, subclass 6.

Group VI. Claim 22, drawn to a method for detecting testis tissue in a patient sample, classified in class 435, subclass 7.21.

Group VII. Claim 23, drawn to a method for detecting a testicular cancer in a patient, classified in class 435, subclass 7.23.

Group VIII. Claim 24, drawn to a method for detecting testis tissue in a patient sample, classified in class 435, subclass 6.

Group IX. Claim 25, drawn to a method for detecting a testicular cancer in a patient, classified in class 435, subclass 6.

4. The inventions are distinct, each from the other because of the following reasons:  
The inventions in groups I-III are disclosed as biologically and chemically distinct, unrelated in structure and/or function, and/or made by and/or used in different methods, and therefore the claimed products are distinct.

The inventions in groups I and III-IX are disclosed as materially different methods that differ at least in objectives, method steps, reagents and/or doses and/or schedules

used, response variables, assays for end products and/or results, and criteria for success, and therefore the claimed methods are distinct.

Inventions in group III and groups VI and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed, namely the antibody can be used in a materially different process of using that product, such as the process of purifying a protein to which the antibody binds by affinity chromatography.

Inventions in group II and group III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed, namely the polypeptide can be used in a materially different process of using that product, such as the process of purifying an antibody, which binds the polypeptide, by affinity chromatography.

The inventions in group I and groups III-IX are not at all related because the products of group I are not specifically used in any of the steps of the claimed methods in groups III-IX.

The inventions in group II and groups IV-IX are not at all related because the products of group III are not specifically used in any of the steps of the claimed methods in groups IV-IX.

The inventions in group III and groups I, III-V, VIII, and IX are not at all related because the products of group III are not specifically used in any of the steps of the claimed methods in groups I, III-V, VIII, and IX.

5. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group

and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. In addition, if electing the invention of Group I or Group III, Applicant is required to elect a single disclosed species of invention encompassed by the following generic claims:

Claim 8 of Group I is generic to a plurality of disclosed patentably distinct species comprising a DNA construct encoding a fusion protein and comprising a first DNA segment encoding a polypeptide comprising a sequence selected from the group consisting of (a) the amino acid sequence of SEQ ID NO: 2 from amino acid 1 to amino acid 31, (b) the amino acid sequence of SEQ ID NO: 2 from amino acid 42 to amino acid 56, (c) the amino acid sequence of SEQ ID NO: 2 from amino acid 108 to amino acid 122, (d) the amino acid sequence of SEQ ID NO: 2 from amino acid 151 to amino acid 165, (e) the amino acid sequence of SEQ ID NO: 2 from amino acid 213 to amino acid 227, (f) the amino acid sequence of SEQ ID NO: 2 from amino acid 42 to amino acid 227, and (g) the amino acid sequence of SEQ ID NO: 2 from amino acid 32 to amino acid 253.

The species of invention are biologically and chemically distinct, unrelated in structure and/or function, and/or used in different methods.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 15 and 16 of Group III are generic to a plurality of disclosed patentably distinct species comprising an antibody and a method for producing said antibody, wherein said antibody is produced by inoculating an animal with a polypeptide selected from the group consisting of (a) a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 from amino acid 32 to amino acid 253, (b) a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 from amino acid 1 to amino acid 253, (c) a

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polypeptide comprising the amino acid sequence of SEQ ID NO: 2 from amino acid 42 to amino acid 56, (d) a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 from amino acid 108 to amino acid 122, (e) a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 from amino acid 151 to amino acid 165, (f) a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 from amino acid 213 to amino acid 227, (g) a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 from amino acid 42 to amino acid 227, (h) a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 from amino acid 34 to amino acid 39, (i) a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 from amino acid 59 to amino acid 64, (j) a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 from amino acid 63 to amino acid 116, (k) a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 from amino acid 58 to amino acid 121, (l) a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 from amino acid 101 to amino acid 107, (m) a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 from amino acid 162 to amino acid 169, (n) a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 from amino acid 194 to amino acid 200, (o) a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 from amino acid 218 to amino acid 225, and (p) a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 from amino acid 249 to amino acid 252.

The species of invention are biologically and chemically distinct, unrelated in structure and/or function, produced by different methods, and/or used in different methods.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

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the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR § 1.143).

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**



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Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### **Conclusion**


10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne (Bonnie) Eyler, Ph.D. can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.  
Examiner  
Art Unit 1642

slr  
February 3, 2004

  
YVONNE EYLER, PH.D.  
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